

Summary of the Invention

The claimed invention is to novel methods for producing novel formulations of foamed glass matrices (FGMs). The methods involve producing a carbohydrate syrup and boiling the syrup to form bubbles and evaporate the solvent. This rapid boiling/evaporation causes the carbohydrates to solidify into very thin sheets that made up the bubbles. This is clearly demonstrated in the drawings accompanying the specification and the response filed Nov. 20, 1996. The large surface area of the FGMs results in ready solubility of the dried compositions and other advantages discussed in the specification and mentioned herein.

Claim Amendments

Claims 1-10, 12-23, 25-34, 36-42, 44-49, 54-59, 61-67, 69-73, 75 and 78-96 are pending. Claims 1, 5, 62, 65, 71-73, 75, 78, 80, 83, 91 and 94 have been amended. Support for the claim amendments can be found throughout the specification and thus do not present new matter. The amendments have been made to advance prosecution of the present application, and are not intended to be a dedication to the public of any subject matter of the claims as originally presented.

Claims 1, 62, 91 and 94 have been amended to more clearly recite that, in step (c), the syrup is boiled to form a liquid foam, and in step (d), the liquid foam is solidified to form a foamed glass matrix, as disclosed on page 19-20 of the specification. Claims 5, 71-73, 75, 78, 80 and 83 have been amended to more clearly recite the claimed invention. No new matter has been introduced. Applicants request that the amendments be entered as they raise no new issues and narrow issues for appeal.

Allowable Subject Matter

Applicants acknowledge with gratitude the Examiner's indication that the subject matter of claims 37-39, 48, 56, 58, 79, 82, 86, 88 and 89 is allowable if written in independent form.

Applicants maintain that the claims from which these claims depend are also patentable, and thus have not rewritten these claims in independent form. Further support for this contention is presented in the sections that follow.

Claim rejections under 35 U.S.C. § 112 ¶ 1

Claims 49, 54-59, 61-69, 72, 73, 75, 81-90, 93 and 96 are rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the disclosure is enabling only for claims using trehalose as the glass forming material. This rejection is respectfully traversed. The standard for enablement requested by the Examiner far exceeds that required by law. Indeed, enablement of only one embodiment is sufficient to satisfy the requirements of 35 U.S.C. § 112, first paragraph. In fulfillment of this obligation, applicants have provided working examples and suggested variations on all the components.

The specification is fully enabling for claims to the glass matrix forming material generically. The claims, as amended, more clearly define the glass matrix-forming material as a stabilizing polyol. The specification defines stabilizing polyols as "those in which a desired substance can be dried and stored without substantial losses in activity by denaturation, aggregation or other mechanisms" (page 7, lines 33-35). Thus, the glass matrix-forming material is more clearly limited to one in which the substance to be stored is stable. In order to satisfy the requirements of 35 U.S.C. § 112, a patent application must teach one of ordinary skill in the art how to make and use the claimed method or composition. The enablement requirement is met if the specification enables any mode of making and using the claimed invention. The Examiner appears to require exemplification of every mode and the exclusion of every non-operable mode. This exceeds the requirement for patentability.

Although some experimentation may be necessary to determine the preferred sugar in a given situation, this would be well within the skill of one in the art given the exhaustive experimental detail found in the specification. There is no evidence that one of skill in the art could not follow the instructions found in the specification to determine whether a particular glass matrix forming material is suitable for use. One of ordinary skill in the art could readily

select a suitable glass matrix forming material, such as a selected carbohydrate, optionally in combination with a substance to be preserved, or a dose of a biological substance, in a suitable solvent such as an aqueous or organic solvent, evaporate the solvent to form a syrup, and then expose the syrup to reduced pressure at a temperature which causes boiling of the syrup. As disclosed in detail in the specification (see, for example, pages 18-20), the selected syrup then may be boiled to form a liquid foam, and then solidified to form a foamed glass matrix. Based on the teachings of the specification, the conditions such as choice of solvent, temperature and pressure, can be designed and optimized for the particular glass matrix forming material used.

The Examiner has stated that Roser (1991) and (1993) indicate that reducing sugars have lower stability than trehalose. However, this does not establish that they could not be used in the method of making a foamed glass matrix claimed by the Applicants. A claimed invention need not be perfect and operable under all conditions. Defense of non-utility by the Examiner must be supported by proof of total inoperability. Merely pointing to potential instances where all carbohydrates may not work is insufficient to establish a 35 USC §112, first paragraph rejection. Thus, this burden has not been met by the Examiner and need not be rebutted by the applicants.

Roser (1991) merely relates to a discussion of the stability of certain compounds dried in the presence of a sugar, and does not relate to a method of obtaining a syrup, or exposure of a syrup to reduced pressure at a temperature which causes boiling of the syrup, or of forming a liquid foam. Roser (1991) further does not suggest or teach solidify a liquid foam to form a solid foamed glass matrix using a carbohydrate. Roser (1991) does not relate to the Applicants' claimed methods and compositions. In fact, Roser provides an example of what was known in the art at the time of filing. It is accepted law that one of skill in the art, wishing to make and use a claimed invention, is in possession of all knowledge in the art at the time of filing. Therefore, one of skill in the art, using the claimed invention to dry a particularly labile protein could use the Roser references to choose a suitable stabilizing polyol. The Roser references thus contribute to the enablement of the invention rather than detract from it. Further, Roser

indicates that there are a wide variety of carbohydrates that would work. This also contributes to enablement.

In the Office Action on page 2, lines 17-19, the Examiner states that Roser states that "reducing sugars should be avoided." In fact, the sentence on page 51 of Roser (1991) states that "reducing sugars are best avoided unless there is good evidence that prolonged exposure to a reducing environment is acceptable...." Thus, Roser does not provide any disclosure that would indicate that the claimed methods of making a foamed glass matrix would not be useful with different sugars. If anything, Roser (1991) suggests that the usefulness of different sugars will depend on the particular application for which the sugar is being used. This is evidence of enablement rather than grounds for finding non-enablement.

Roser (1993), cited by the Examiner, merely suggests that some restriction enzymes are unstable when they are dried in the presence of reducing sugars, and then heated for over one month to test stability. Roser (1993) relates to a study of the long term stability of restriction enzymes stored at elevated temperatures, wherein stability corresponds to enzyme activity. The observation that some restriction enzymes lose enzyme activity when stored in reducing sugars at elevated temperatures over many days does not suggest that the Applicants' claimed method of making foamed glass matrices would not be enabled for a variety of carbohydrates as claimed. With respect to this reference, the Examiner states, "the instant claims recite storage of biological substances in general, thus this recitation includes all those that may or may not be as sensitive as Pst I, further, such recitation also includes those that may be more sensitive than Pst I, in which case the claims are clearly not enabled." This is not the requisite standard to establish a 35 USC §112, first paragraph rejection. The standard of enablement required for patentability does not require that every possible embodiment encompassed by a claim be operable. There will be some carbohydrates which form FGMs but in which restriction enzymes are not stable. This does not render the claimed invention non-enabled. In fact, the

Examiner's comment acknowledges (as if it were necessary) that there are operable embodiments. This is sufficient to render the claims enabled.

Even if some experimentation were required to find the proper combination of stabilizing polyol and material to be stored in the FGMs, it is well settled that some experimentation does not constitute undue experimentation. One of skill in the art could turn to publications available at the time of filing to choose various carbohydrates and then follow the well described methods in the specification to produce the FGMs. Stability measurements are well known in the art and can be easily determined by one of skill in the art. No evidence has been presented to indicate that making such choices and performing such experiments is beyond the skill of one in the art. In fact, references have been cited that provide suitable carbohydrates and substances to be preserved. Further, the specification provides a variety of working examples. The claims, particularly as amended, are thus patentable under 35 USC §112, first paragraph.

A further rejection is made under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not teach modifying the carbohydrate chemically or enzymatically. This presumably refers to claim 5. In order to sustain such a rejection, the Examiner must show that one of skill in the art could not make such modifications. Not every experimental detail need be provided in a specification as one of skill in the art is presumed to know standard procedures. It is well within the skill of the ordinary artisan to modify carbohydrates using readily available materials and according to knowledge in the art. Also, many of these modified carbohydrates are commercially available. The artisan will readily appreciate that the list of exemplary carbohydrates on page 8 of the specification includes those obtained "by reduction" and by other chemical and enzymatic procedures, and that procedures not indicated or implied in the disclosure are nonetheless incorporated in the scope of the invention.

In fact, the skilled artisan has available a wide variety of publications with information as to types of modifications and methods of making such modifications. Accompanying this amendment is a Supplemental Information Disclosure Statement and a number of representative, but not exhaustive, publications related to carbohydrate modifications. Several articles are general. For instance, *Organic Chemistry*, by Streitwieser, Jr. and Heathcock eds. is a standard chemistry textbook published in 1976. An entire chapter is provided and discusses sugars in general and a wide variety of modifications. The *Angewandte Chemie* article entitled "Advances in Selective Chemical Syntheses of Complex Oligosaccharides", published in 1982, discusses chemical syntheses of complex carbohydrates and provides a number of modifications. The article entitled "New Methods for the Synthesis of Glycosides and Oligosaccharides - Are There Alternatives to the Koenigs-Knorr method?", published in 1986 provides a number of possible modifications and methods of making the modifications. More specific carbohydrate modifications are discussed in the following:

Prey, US Patent No. 3,956,278 "Novel Mixed Partial Esters of Carbohydrates" (1976)

Goren and Jiang, "(α -D-Glucopyranosyluronic acid) (α -D-Glucopyranosiduronic acid) and Simple Derivatives" (1980)

Takahiko et al., EP Patent Application No. 0,714,905, "Process for Producing Trehalose Derivatives" (1996)

Junji et al. EP Patent Application No. 0,356,154 "Trehalose Derivatives" (1990)

Nishikawa et al. US Patent No 4,684,719 " α , α -Trehalose Fatty Acid Diester Derivative" (1987).

Thus, it is clear that a wide variety of modifications and methods of making such modifications are available to one of skill in the art wishing to make and use the claimed invention. There is no evidence that one of skill in the art could not use these or other

publications known in the art at the time of filing to make and use the invention as claimed. Consequently, the claims are enabled under 35 USC § 112, first paragraph.

The Examiner states on page 4, lines 3-12 that the specification does not teach how carbohydrates can be chemically or enzymatically modified, and that the list of carbohydrates on page 8 is a list of compounds which are already modified. Claim 5 as amended is directed to the embodiment of claim 3 wherein the carbohydrate is a “chemically or enzymatically modified carbohydrate”. Thus, applicants are not reciting or claiming a method of making modified carbohydrates. Applicants are claiming a method of making a glass forming matrix material optionally using modified carbohydrates, they are not claiming methods of modifying carbohydrates. As described in detail in the specification, such modified carbohydrates can be obtained commercially, or made using methods which are well developed in the art. Applicants need not teach what is known in the art. Thus, based on the teachings of the specification and the general knowledge in the art at the time of filing, one of ordinary skill could readily practice the claimed methods using different modified carbohydrates.

Claim rejections under 35 U.S.C. § 112 ¶ 2

Claims 1, 5, 9, 71-73, 75 and 80 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The claims have been amended to more clearly define the invention. Applicants traverse these rejections to the extent they are applied to the amended claims.

Claim 5, as amended, recites the embodiment of claim 1 wherein the carbohydrate is a “chemically or enzymatically modified carbohydrate”. Claim 5 as amended is definite in accordance with the requirements of 35 U.S.C. § 112, second paragraph. One of ordinary skill in the art could readily determine the scope of the “chemically or enzymatically modified carbohydrate” claimed based on the disclosure of the specification and the knowledge available in the art at the time of filing. Modified carbohydrates may be made using readily available

materials and according to knowledge in the art. Also, many of these modified carbohydrates are commercially available. The ordinary artisan will readily appreciate that the list of exemplary carbohydrates on page 8 of the specification includes those obtained “by reduction” and by other chemical and enzymatic procedures well established in the art. No evidence to the contrary has been provided by the Examiner. As shown in the attached references, various modified carbohydrates and methods of making such carbohydrates are known in the art.

The Examiner also has indicated that claim 9 is indefinite for failing to further limit claim 8. Claim 8 is directed to the embodiment wherein the solvent is “aqueous,” and claim 9 is directed to the embodiment wherein the solvent is selected from “biologically acceptable buffers”. The Examiner has stated that “aqueous solvent and aqueous buffer solvent are seen to be the same.” Applicants respectfully traverse. Claim 9 is definite since it requires that the aqueous solvent be a “aqueous buffer solvent”. Buffered aqueous solvents are well known in the art as being a particular form of an aqueous solvent. Buffers are known to be substances which in solution resist a change in hydrogen ion concentration upon the addition of acid or alkali. The specification discloses that “the aqueous solvent includes any suitable aqueous solvent known in the art, including, but not limited to, water and biological buffer solutions” (page 10, lines 10-13). Thus, based on the teachings of the specification and knowledge generally available in the art, claim 9 is directed to an embodiment of the invention which is further limited than the embodiment of claim 8.

The Examiner has suggested that in claims 71-73 and 75 the term “obtainable” should be amended to recite “obtained” to make the claims into more definite form, and that the abbreviations “GPS” and “GPM” be replaced with the full names in claim 80. Solely to promote prosecution of the above-referenced application, claims 71-73 and 75 have been amended to replace “obtainable” with “obtained” in the amendments to the claims herein.

Additionally, the abbreviations "GPS" and "GPM" have been replaced with the full names of the carbohydrates in claim 80.

Claim rejections under 35 U.S.C. § 102

The Applicants wish to thank the Examiner for his withdrawal of the rejections of claims 71 and 72 under 35 U.S.C. § 102(b) in view of Wettlaufer et al. (U.S. Patent No. 5,290,765).

Claims 1-4, 6, 8, 9, 13-18, 24, 30-34, 36, 40, 41, 49, 54, 55, 62, 63, 71, 72, 78, 83-85, 90-91 and 93 were rejected under 35 U.S.C. § 102(b) as being anticipated by Chivers (U.S. Patent No. 3,557,717). As discussed below, Chivers is from nonanalogous art and is thus improperly cited against the claimed inventions. Nonetheless, even if applied, it would not anticipate the claimed invention.

To more clearly recite the methods and compositions of the invention, in accordance with the Examiner's suggestion, independent claims 1, 62, 65, 91 and 94 have been amended to recite that in the method in step (c), the syrup is boiled to form a liquid foam, and in step (d), the liquid foam is solidified to form a foamed glass matrix, as described for example on page 19, lines 14-25 and page 20, lines 10-19 of the specification. This addresses the Examiner's comment that Applicants' previous arguments were not persuasive because the step of hardening while still a foam was not in the claims.

Applicants traverse the rejections under 35 U.S.C. § 102(b), to the extent they are applied to the claims as amended. For a rejection to be valid under § 102(b), a reference must teach within its four corners all the features of the method or composition which is claimed. The disclosure of Chivers does not attain this standard. Chivers teaches a process for making cotton candy from a solution slurry or syrup containing sugar and water, which is cooked and then sprayed from a discharge opening to convert it to cotton candy. Chivers discloses at col. 1,

lines 5-10, that sugar floss is in the form of fine fluffy filaments of sugar. Anyone who has eaten cotton candy knows that it is a rather ephemeral substance that rapidly forms a sticky goo on the hands, face and any other surface it comes in contact with. Moreover, nothing in Chivers suggests the formation of a liquid foam, nor of hardening a liquid foam to form a solid foamed glass matrix. This is acknowledged by the Examiner with respect to the 35 U.S.C. § 112, first paragraph rejection. For example, the Office Action states, "the method of the prior art is not the same as the method of the instant invention" (page 3, lines 25–26).

The claims under examination recite foamed glass matrices (FGMs), methods of making FGMs, methods of reconstituting FGMs, and products obtained by reconstituting FGMs. The specification defines an FGM as a "high surface area *foamed* glass matrix". An FGM is less dense than the solid amorphous glass, because of the increased surface area and the thinness of glass forming the *bubble walls* of the foamed glass matrix (page 7, lines 20-27; emphasis added). As recited in claim 1, FGMs are typically formed by obtaining a syrup, exposing the syrup to conditions that cause boiling to form a liquid foam, and then solidifying the liquid foam to form a foamed glass matrix.

FGMs are novel over all prior art teachings of which Applicants are aware, including the reference cited in the Office Action under § 102. Chivers teaches an apparatus and process for making cotton candy, which is defined in Chivers as candy in the form of fine fluffy *filaments* of sugar (column 1, lines 6-7). Chivers does not teach a hardened foam. As noted above, Chivers provides a fluffy candy material that rapidly absorbs water and becomes a sticky mess. The Examiner appears to be making an inherency argument based on the contention that, "the glassy state is an inherent property of sugars" (Office Action page 3, line 27). In order to support an inherency argument, however, it must be shown that the claimed invention is necessarily present in the prior art reference. The claimed invention, a dry, foamed matrix, is completely different from cotton candy and thus is not necessarily produced by the prior art

method. While sugars are able to be processed into a glassy state, there are a wide variety of differences in the product. In the present invention, it is not merely the glassy state of the FGM that contributes to the benefits of the composition. As described in the specification, the foamed nature of the material provides advantages over thick, unfoamed glasses and the filamentous state of compositions such as cotton candy.¹ Moreover, the FGMs result in greater stability and solubility compared to the products obtained by lyophilization. Many of these advantages are enumerated in the specification, they need not be enumerated in the claims as they are inherent in the physical makeup of the claimed compositions.

Since none of the references teach formation of a solid foam, and since the rejected claims involve formation of a solid foam, the rejection is overcome. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim rejections under 35 U.S.C. § 103

Claims 10, 12, 19-23, 25-29, 42, 44-47, 57, 59, 61, 64-67, 69, 70, 73, 75, 81, 86-87, 94 and 96 are rejected under 35 U.S.C. § 103 as unpatentable over Chivers in view of Black (U.S. Patent No. 3,619,294), Samuels et al. (U.S. Patent No. 5,422,384) and Wettlaufer (U.S. Patent No. 5,290,765). Claims 7, 80, 93 and 95 are rejected under 35 U.S.C. § 103 as unpatentable

¹ For instance, page 6, lines 5-26 gives the following benefits of the claimed compositions.

The methods of this invention result in products with markedly reduced residual moisture content compared to thick, unfoamed glasses, resulting in a drier product with increased stability and higher glass transition temperatures. Further, the high surface area afforded by FGMs results in significantly increased dissolution rates on reconstitution. This is especially useful for low solubility substances such as organic substances, including, but not limited to, Cyclosporin A, lipids, esterified sugars, beta blockers, H2 agonists and antagonists, steroids, sex hormones, phenobarbitals, analgesics, antimicrobials, antivirals, insecticides, pesticides and the like. These methods produce products which provide all of the benefits and none of the drawbacks of freeze-drying. These drawbacks include, but are not limited to, long and energy-intensive drying processes using extremely low temperatures and increased product dissolution times. The products encompassed by the present invention are rapidly dissolved, with complete solubilization of the product that can be easily determined visually. The methods are straightforward, standardized, and reproducible.

over Chivers in view of Black, Samuels et al. and Wettlaufer, and further, in view of Roser (GB 2,206,273).

Applicants traverse these rejections. The rejections are insufficient to establish unpatentability for at least the following reasons: 1) the references are from non-analogous arts; 2) the references alone do not teach or suggest the claimed invention; 3) there is no motivation to combine the references; and 4) even if combined, the references do not teach or suggest the claimed foamed glass matrices or methods for their manufacture.

To establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available in the art of the claimed invention. If references are combined, there also must be a motivation to combine reference teachings. Further, there must be a reasonable expectation of success. The initial burden is on the Examiner to establish that there is some suggestion of the desirability of doing what the inventor has done. Either the references must expressly or impliedly suggest what the inventor has claimed, or the Examiner must present a convincing line of reasoning why the invention is obvious. MPEP 2142. Once a case of prima facie obviousness is established, the burden shifts to the inventors to provide rebuttal evidence. In this case, prima facie obviousness has not been established, thus it is not incumbent on the inventors to provide additional evidence of patentability. Indeed, since a combination of the references does not teach or suggest the claimed invention, it would not be technically possible to provide comparison data.

The grounds provided in support of the rejection are that "the references teach all of the reagents and steps involved in the instant method, therefore, it would have been obvious that when combined, the prior art method would produce the same or obvious variation of the same product of the instant invention" (Office Action, page 10, lines 13–16). This is not the proper

standard of obviousness. Rather, it is practically a definition of hindsight.² Even if this were the proper standard for obviousness, no explanation is provided as to how the combined references would yield the claimed invention. As pointed out previously, and shown in detail below, the combined references (for the purposes of argument only, not in acquiescence to the grounds of rejection) simply do not teach or suggest the claimed invention.

It is well established that teachings under disparate arts cannot be combined for purposes of a rejection under 35 U.S.C. § 103, absent a teaching or motivation to do so.³ The teaching or motivation must occur without the benefit of hindsight from the application under consideration.

The references are from non-analogous art. The determination of whether art is analogous requires determination of whether a reference is from the same field of endeavor, regardless of problem addressed; and if not, whether the reference is nonetheless reasonably pertinent to the particular problem with which the inventor is involved. Whether the field of endeavor is the same turns not on whether teachings are from the same industry, but the objective of the invention. The claimed invention of the present application and the art cited in the Office Action are from a number of different fields of endeavor, and lack sufficient motivation to be combined.

The claimed invention relates to foamed glass matrices and methods of preparation thereof. As stated in the disclosure, foamed glass matrices are particularly useful for storing substances. As a storage vehicle, FGMs represent a substantial advance over those previously

² "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicants' structure as a template and selecting elements from references to fill the gaps." *In re Gorman* 18 USPQ2d 1885 (Fed. Cir. 1991).

³ "The combination of elements from non-analogous sources, in a manner that reconstructs the applicants' invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness." *In re Oetiker* 24 USPQ2d 1443 (Fed. Cir. 1992).

used for a number of reasons, including the ease of formation, stability imparted to the stored substance, the low moisture content achievable, and the ease of reconstitution.

The foamed glass matrices are prepared by combining a glass matrix-forming material in a solvent therefor, evaporating the solvent, and exposing the syrup to reduced pressure at a temperature that causes boiling of the syrup to form a liquid foam and solidifying the liquid foam to form a foamed glass matrix. Chivers teach apparatus and methods for the preparation of cotton candy. This is clearly non-analogous art. Additionally, the art clearly does not provide motivation to form a solid foamed glass matrix. This lack of analogy is said to be overcome by the Examiner on the ground that "Chivers in view of Black in seen to render the instant claims obvious" (Office Action, page 9, lines 13–14). This does not address the use of the Chivers reference as analogous art; rather, it addresses the conclusion that is drawn once the reference is used. The standard for determination of analogous art is not limited to elements of the claimed invention but, as noted above, is determined by the field of endeavor and the problem with which the inventor is involved. Chivers addresses the candy art, specifically cotton candy; this is neither the same field as that of the present invention, nor does it address the problem with which the inventor was involved. Therefore, Chivers is inappropriately combined with Black, regardless of the conclusions that can be drawn.

The contention that applicants' previous arguments regarding non-analogous art were unpersuasive because the differences noted are "not recited in the rejected claims," has no basis in law. The invention must be looked as a whole, taking into account the specification. Clearly, the problems sought to be solved by the claimed invention (read in light of the specification) were different and unrelated to the problem Chivers sought to solve when building a better cotton candy machine.

Likewise, Black sought to solve a different problem, that of impregnating crystalline sugar with additives or modifying agents. The Examiner defends the use of the Black reference

on the ground that it "is not relied upon for the teachings of product structures, but is relied upon for the teachings of volatile organic solvents, viscosity agents and medicinal components" (Office Action, page 10, lines 9–11). This virtually acknowledges the correctness of applicants original observation that Black is non-analogous art inasmuch as the subject matter claimed has to be ignored in order for the Examiner to justify use of the reference. Black discusses the use of these components for impregnating granules of sugar crystals, not for anything related to the claimed invention. Therefore, the use of Black is inappropriate to support a 35 U.S.C. § 103 rejection.

Even if combined, and this would not be appropriate, Chivers and Black could only be construed to teach a method of making either cotton candy with additives or crystalline sugar for consumption as a candy. Neither is remotely related to the claimed invention. Neither would teach or suggest the claimed invention. Therefore, an objective analysis of the art shows that it does not teach or suggest the claimed invention.

Samuels et al. teach glass polymer composites and methods of making them. The list of organic and inorganic polymers for use with the Samuels invention listed in column 3, line 60 ff. are all covalent polymers. The working examples Samuels are all conducted with polybis(dimethylamino)-phosphazine, an inorganic covalent polymer. This is structurally different from typical embodiments of the present invention. The objective of Samuels et al. is to provide polymer/glass or polymer/ceramic composites with increased thermal stability, chemical stability, and enhanced fracture toughness, for use, for example, as fire retardants optical windows, and protective coatings. Accordingly, Samuels is non-analogous and irrelevant art in relation to the claimed invention.

Samuels discloses that the molecular phase polymer/glass composite materials disclosed therein are formed by mixing a solution of a glass with a polymer to form a homogenous mixture, removing the solvent, and then heating the homogenous mixture to form bonds at the

molecular level between the glass and the polymer (col. 2, lines 13-22). Samuels further discloses that the materials can be used in dip coating, spin casting, melting and extruding to form coatings, films, sheets and fibers (col. 2, lines 23-35). Thus, nothing in Samuels teaches or suggests the claimed foamed glass matrices or methods for making them. In view of Samuels, there would be no motivation to form a liquid foam and solidify it to form a solid foamed glass matrix.

The Examiner supports the use of the Samuels reference on the same illogical grounds as the other references. That is, because there is something useful to his argument, any discrepancies or evidence of its non-analogous nature are irrelevant.⁴ This reasoning is flawed. The reference must first be shown to be in an analogous art and then it can be used to support a rejection. Even if the Samuels reference were applicable, its combination with the other references would not yield the claimed invention.

While it may be "known in the art that increased temperature and pressure are routinely used to evaporate solvents from a mixture", this knowledge does not teach or suggest the evaporation of solvents from a syrup so as to boil the syrup and create an FGM. Evaporation of solvents from Chivers would still produce cotton candy, evaporation from Black would still produce only impregnated crystals.

In summary, Chivers teaches hardened sugar in a filamentous form. Either alone or in combination with the other references, Chivers does not teach or suggest FGMs. Samuels et al. teach covalent polymers hardened into a glass or ceramic. Either alone or in combination with the other references, Samuels does not teach or suggest FGMs. Black et al. teach impregnated

⁴ The Office Action, page 9, lines 2-26 states:

Applicant argues that Samuels et al teach glass making methods and composition and thus is non-analogous art. This argument is not persuasive because the Samuels et al reference is used to teach evaporation of various solvents using increased temperature and pressure and not for the teachings of polymers used in glass making. Samuels et al show that it is conventional and well known in the art that increased temperature and pressure are routinely used to evaporate solvents from a mixture.

microcrystalline sugar granules. Either alone or in combination with the other references, Black does not teach or suggest FGMs.

Wettlaufer et al. teach drying biological materials in the presence of vitrifying solutes. The Wettlaufer drying method comprises, "drying said combination, [cells and vitrifying solutes] by exposing said combination to a desiccant, at a temperature above that at which said combination will freeze and below that at which said vitrifying solutes achieve the vitrified state, at approximately normal atmospheric pressure, until said combination is substantially dry ..." Column 7, lines 36-41. Wettlaufer thus provides drying under desiccation, not boiling to produce an FGM. Wettlaufer describes the necessity of obtaining a vitreous dried product rather than a crystalline product but solves this problem by choosing substances that "will form a glassy solid state under certain conditions." Column 6, lines 28-29. Wettlaufer further describes avoidance of crystallization:

As any solution dries down, the molecules in the solution can either crystallize, or they can vitrify. A solute which has an extensive asymmetry may be a superior vitrifier, because of the hindrances to nucleation of crystals during drying. As noted above, the addition of raffinose inhibits the crystallization of sucrose, and hence improves the protective effects.

At best, Wettlaufer can be said to identify a problem, the need to keep carbohydrates in a vitreous form. The solutions provided by Wettlaufer do not teach or suggest the claimed invention. Mere identification of a problem to be solved does not render an invention that solves the problem obvious. Wettlaufer in combination with Chivers would still produce cotton candy and the combination of Wettlaufer with Block would be inappropriate as one is directed to reducing crystallization and the other is directed to processing crystals. The combination is simply not plausible. A combination of Wettlaufer and Samuels, if appropriate, and it is not, would suggest only the Wettlaufer drying/desiccation method for removing solvents. Thus, none of these combinations would teach or suggest the claimed invention. Either alone or in combination with the other references, Wettlaufer does not teach or suggest FGMs.

Roser (GB 2,206,273) teaches impregnating foodstuffs with trehalose, and then drying the foodstuffs by heating. Either alone or in combination with the other references, Roser does not teach or suggest FGMs. The Examiner states that, "[i]t would have been obvious for one of ordinary skill in the art at the time the invention was made to use the trehalose, as taught by Roser, in the method of Chivers because Roser shows that trehalose is more efficient than other sugars and does not render the product too sweet." As noted repeatedly, Chivers discusses methods for making cotton candy. The combination of a food storage method with a candy making method is inappropriate. Even if the combination were appropriate there is no motivation to do so. Why would one store food in the form of cotton candy? Conversely, why would one want cotton candy that is more "efficient" or less "sweet"? Even if the combination were made, the production of stored food in cotton candy form or of efficient and less sweet cotton candy in no way teaches or suggests the claimed invention. The claimed invention is thus patentable over the cited art either alone or however inappropriately combined.

The claims under examination involve foamed glass matrices which are novel and unobvious over the prior art of record. Accordingly, the invention is patentable over the references cited in the Office Action. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

Following this amendment and the remarks made herein, Applicants submit that the present application is in condition for allowance. Applicants respectfully request that all rejections be withdrawn and that all claims currently under consideration be allowed.

If a telephone interview would be of assistance in advancing prosecution of the present application, the Examiner is invited to telephone Applicants' attorney at the number indicated below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 5, 1997

Respectfully submitted,

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